EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**CIVIL ACTION NO. 2:12-md-02327**
	MDL No. 2327
This Document Applies To:	Judge Joseph R. Goodwin
***Mullins, et al. vs. Ethicon, Inc., et al.*, 2:12-cv-02952, and each of the consolidated cases identified in Exhibit A**	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS OF DR. REBECCA M. RYDER

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' expert, Rebecca M. Ryder, M.D. ("Dr. Ryder").

INTRODUCTION

Dr. Ryder is a medical doctor board certified in obstetrics and gynecology with a subspecialty certification in pelvic floor medicine and reconstructive surgery. *See* Ex. B, Expert Report of Rebecca M. Ryder, M.D., MDL General Report —TVT ("Ryder Expert Report") at 1; Ex. C, Curriculum Vitae of Rebecca M. Ryder, M.D. ("Ryder CV"). Plaintiffs do not challenge her qualifications as such. However, Dr. Ryder opinions far exceed the bounds of her qualifications and are founded on insufficient facts and unreliable methodology. *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (holding that the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue).

Dr. Ryder's experience in the field of obstetrics and gynecology, with a subspecialty certification in pelvic medicine and reconstructive surgery, does not render all of her opinions

admissible. The admissibility of Dr. Ryder's unfounded opinions is contrary to law and presents serious risks of confusing the issues and misleading the jury in this case. *See Westberry v. Gislaved Gummi AB,* 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'") (citing *Daubert v. Merrell Dow Pharms.,* 509 U.S. 579, 596 (1993)). Moreover, as this Court noted, "[just because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'" *Cisson v. C. R. Bard, Inc. (In re C. R. Bard, Inc.),* 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). Accordingly, Dr. Ryder should be prevented from offering testimony or opinions that exceed those permitted under the federal rules and *Daubert* and its progeny.

PRELIMINARY AND FACTUAL STATEMENT

A. Dr. Ryder's Educational Background

Dr. Ryder completed her medical degree at the University of North Carolina at Chapel Hill in 1989. Ex. C, Ryder CV. She then completed a residency program in Obstetrics and Gynecology at the same institution in 1993. *Id.* Dr. Ryder has not completed a residency program in either general surgery or urology or a Fellowship recognized by the Accreditation Council for Graduate Medical Education in any area of medicine. Ex. D, Dr. Rebecca Ryder 3/21/16 Dep. Tr. ("Ryder 3/21/16 Dep. Tr.") at 21:3-15; 20:20-24; 21:1-2. During her residency training in obstetrics and gynecology, Dr. Ryder had not heard of transvaginal mesh as a use of treatment for pelvic organ prolapse ("POP") or stress urinary incontinence ("SUI"). *Id.* at 27:9-13. Dr. Ryder received her subspecialty certification in

female pelvic medicine and reconstructive surgery in 2013. *Id.* at 21:16-19. She was "grandfathered" in and did not have to complete a Fellowship to receive her certification in this area. *Id.* at 21:20-23. Dr. Ryder obtained her subspecialty certification in 2013. Ex. C, Ryder CV.

Dr. Ryder has never taken graduate level classes in the areas of engineering, material sciences or polymer materials.' Ex. D, Ryder 3/21/16 Dep. Tr. at 24:17-21; 25:12-17. Moreover, she has never engaged in academic research that was the basis for a thesis in order to obtain any type of graduate degree in any area of study. *Id.* at 23:20-23.

B. Dr. Ryder's Lack of Research with Transvaginal Mesh

Dr. Ryder has never been a clinical trial manager or a clinical trial leader for a study using transvaginal mesh. *Id.* at 28:15-19. Further, she has not published a peer reviewed article directly addressing the use of polypropylene as a transvaginal surgical treatment for SUI or POP. *Id.* at 28:10-14. Lastly, Dr. Ryder is not currently a peer reviewer for any scientific or medical journal. *Id.* at 27:19-21. Even during her time as a peer review, Dr. Ryder never reviewed an article dealing with transvaginal mesh. *Id.* at 28:7-9.

ARGUMENT

I. Dr. Ryder's should not be able to hide behind her deficient "reliance" list, and all opinions proffered by Dr. Ryder based on unknown facts or data should be excluded.

Dr. Ryder—like all experts—was required to provide Plaintiffs with a list of documents that she has reviewed and relied upon in forming her opinions. *See* Fed. R. Civ. P. 26(a)(2)(B)(i) and (ii) (requiring disclosure of an expert's opinions, including the basis for such opinions, and the facts or data considered by the witness in forming such opinions). Dr. Ryder, however, effectively admitted that her reliance list is not actually a disclosure of the basis, facts, or data

she relied upon in forming her opinions; but rather, is simply a list of all documents sent to her by Defendants' attorneys—and that she did not even read all of these documents. Ex. E, Dr. Rebecca Ryder 7/11/16 Dep. Tr. ("Ryder 7/11/16 Dep. Tr.") at 69:12-70:9. And she did nothing to confirm that the reliance list provided to Plaintiffs' counsel accurately revealed the documents that she had in fact reviewed. *Id.* at 70:24-71-6.

As such, the failure of Dr. Ryder and Defendants to provide a proper reliance list, in conformity with the Federal Rules of Civil Procedure, was the product of neglect not allowable under any provision of the Rules. The effect of this failure is prejudicial to Plaintiffs as Plaintiffs are unable to determine the basis for any of Dr. Ryder's opinions expressed in her expert report, save those opinions that are cited. Plaintiffs should not be forced to search for a needle in a haystack in an effort to prepare for trial. As such, all of Dr. Ryder's uncited opinions expressed in her expert report should be excluded.[1]

II. Opinions Regarding Defective Design

In her expert report, Dr. Ryder opined the following:

> Based on my review of the reported success and complication rates discussed in the peer-reviewed medical literature, and based on my experience as a pelvic floor surgeon, TVT's benefits far exceed its risks, and for that reason, **it is not defectively designed**.

Ex. B at 30 (emphasis added). But any opinions from Dr. Ryder regarding whether or not the TVT is defectively designed should be excluded because (1) Dr. Ryder is not qualified to render such opinions and (2) the opinions have no reliable, scientific basis.

[1] Plaintiffs note that it would be well within the Court's discretion to exclude Dr. Ryder's testimony entirely for failing to comply with the Federal Rules on expert disclosures. *See, e.g., Meyers v. Nat'l R.R. Passenger Corp.*, 619 F.3d 729, 734 (7th Cir. 2010) (noting that the purpose of expert disclosures is to allow opposing side to prepare a response, and the consequence for noncompliance with Rule 26(a)(2)(B) is "exclusion of an expert's testimony" unless the failure was substantially justified or harmless). Here, Defendants' failure to comply with Rule 26(a)(2)(B) is neither substantially justified nor harmless, and therefore, Dr. Ryder's testimony may be excluded in its entirety.

Dr. Ryder has never designed a medical device nor has she ever acted as a consultant regarding device design. Ex. E, Ryder 7/11/16 Dep. Tr. at 79:16-21. Moreover, Dr. Ryder has previously testified that she does not know what any of the following are: design control, design requirement matrix or FNEA. Ex. D, Ryder 3/21/16 Dep. Tr. at 108:11-19. Similarly, although she "may have run across" DDSA, she could not recall what it means. *Id.* at 108:20-22. These are all common terms that an expert opining to a product's defectiveness should, and would, know. Moreover, Dr. Ryder's CV shows that she: has never participated in development of any pelvic mesh device; has not authored a single peer-reviewed article on using polypropylene as a transvaginal surgical treatment for SUI or POP, let alone an article on the design, safety or efficacy of pelvic mesh products; and, has never managed, led or even participated in a clinical trial regarding the design, safety or efficacy of pelvic mesh products. *See* Ex. C, Ryder CV. Dr. Ryder also previously testified to as much in a deposition. *See* Ex. D, Ryder 3/21/16 Dep. Tr. at 28:7-19.

In addition to Dr. Ryder being unqualified to opine to defective design, her opinions are also unreliable. Not only is Dr. Ryder's expert report wholly devoid of how she reached the conclusion that TVT is not defectively designed, but it also contains no mention of the scientific methods, controls and veracity of the analysis she employed in reaching her opinion. Dr. Ryder did not even indicate or cite other peer-reviewed studies or methodologies on which she relied in forming her opinion. In other words, Dr. Ryder's opinion is not based on any methodology or scientific support, let alone reliable methodology. As such, this opinion must be excluded as unreliable. *See Foster v. Legal Sea Foods, Inc.,* No. CCB-03-2512, 2008 U.S. Dist. LEXIS 57117, at *30 (D. Md. July 25, 2008) ("A court will not credit an expert witness who testifie[s] to no customs of the trade, refer[s] to no literature in the field, and [does] not

identify [relevant principles]; but merely [gives] his own subjective opinion.") (alteration in original) (quoting *Freeman v. Case Corp.*, 118 F.3d 1011, 1016 (4th Cir. 1997).

Despite these admissions and Dr. Ryder's obvious lack of relevant education, background, training, and experience, Defendants are nevertheless attempting to "slip in" an expert opinion that is unreliable and one that Dr. Ryder is not qualified to give. Dr. Ryder's opinions on defective design amount to nothing more than baseless assumptions, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent. *See Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, at *3 (4th Cir. Sept. 8, 1997) ("[T]he expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation.").

III. Opinions Regarding Polypropylene Mesh Material, Mesh Pore Size, And Risk of Infection

Dr. Ryder's opinions regarding the use of polypropylene material, mesh pore size, and risk of infection must be excluded because: (1) Dr. Ryder is not qualified to render such opinions; (2) the opinions have no reliable scientific basis; and (3) the opinions violate Fed. R. Civ. P. 26(a)(2)(B)(i). In her expert report, Dr. Ryder opined the following:

> Based on my review of the medical literature and my experience with the device, the PROLENE mesh used in TVT is an appropriate, effective and safe material for use in this indication. Polypropylene mesh and sutures have been used an implant for decades. The pore size is sufficiently large to allow for proper tissue ingrowth, and has not presented increased risks of infection

Ex. B, Ryder Expert Report op. 2, at 30. For purposes of this Motion, Plaintiffs seek exclusion of opinion 2 in its entirety.

Dr. Ryder is unqualified to render opinions regarding the mesh material's appropriateness, effectiveness, and safety. Dr. Ryder is also unqualified to opine that "[t]he pore size is sufficiently large to allow for proper tissue ingrowth, and has not presented

increased risks of infection." Dr. Ryder does not have any experience in material science and has never analyzed, tested or studied polypropylene mesh. Ex. E, Ryder 7/11/16 Dep. Tr. at 78:23-79:4; *see also*, Ex. D, Ryder 3/21/16 Dep. Tr. at 24:17-21; 25:12-17; 28:10-19, or apparently reviewed literature on the subject, yet she arbitrarily offers opinions regarding the properties of polypropylene used in Ethicon mesh products. But Dr. Ryder admits that she is not a biomaterials expert—and that she does not know anything about the differences in polypropylene used in medical devices. Ex. E, Ryder 7/11/16 Dep. Tr. at 77:9-78:7.

Even if this Court determines that Dr. Ryder is qualified, the opinions should be excluded as unreliable. Dr. Ryder's report contains no methodology or citation to peer-reviewed articles for her conclusions regarding pore size and risk of infection. Moreover, the report contains no evidence or mention of Dr. Ryder performing any analysis or comparison of implants to reach her conclusions. Since these opinions are unverifiable, are without scientific basis, and amount to unsupported speculation, they should be excluded as unreliable.

IV. Opinions regarding the differences, or "clinical significance" of mechanical cut mesh versus laser cut mesh should be excluded

Dr. Ryder seeks to opine that neither the literature nor her clinical experience reveals any support for the assertion that the properties, or clinical outcomes, of mesh are effected by whether it is mechanically or laser cut. More specifically, Dr. Ryder seeks to tell the jury:

> There is no evidence to suggest that the safety of TVT mesh is affected by whether it is mechanically-cut or laser-cut. There is no medical literature that assesses this. I have used both the mechanically cut and laser cut mesh and have found no change in clinical outcomes between the two products. I have not seen particle loss, roping or fraying on repeated clinical examinations of hundreds of women implanted with midurethral slings.

Ex. B at op. 5, p. 31. But this opinion finds no support or basis in either Dr. Ryder's clinical practice, or her review of the literature and evidence.

A. Dr. Ryder's clinical experience does not support any opinion regarding mechanical cut versus laser cut mesh.

As an initial matter, despite her reference to what she has "seen" during her "clinical examination of hundreds midurethral slings," (*id*.) the real question at issue here is what she knows about the differences between the laser cut and mechanically cut TVT. She admits that number is much less—around 40 over the course of the last 8 years. Ex. E, Ryder 7/11/16 Dep. Tr. at 75:19-76:4. Indeed, Dr. Ryder herself admits that such a small number of patients has no medical or scientific significance:

> Q. Okay. And so what significance is there across a population of women that something less than 40 TVT mechanically cut devices that were implanted by a single physician in Virginia over an eight-year period, that she has not seen roping of the device? Does that have any bearing on epidemiology or population-wide problems associated with the device?
>
> THE DEPONENT: That single piece of data? No.

Id., see also 86:24-87:8.

Moreover, there certainly cannot be a medical or scientific significance gleaned from Dr. Ryder's claim that she has not "seen" any clinical difference (*e.g*. roping, curling, fraying, particle loss) between mechanically cut and laser cut mesh in these 40 or so women where Dr. Ryder does not track whether the mesh that she is implanting is mechanically cut or laser cut—and she has made no effort to compare or contrast the different outcomes:

> Q. Okay. Have you tracked within the patients whom you've implanted the TVT-R, how many of those receive the mechanical cut and how many of them receive the laser cut?
>
> A. I have not tracked that, no.
>
> Q. So it's fair to say you don't know how many TVT mechanically cut you have implanted in your career. Correct?
>
> A. Correct.

Q. And you don't know how many laser cuts you have implanted in your career. Correct?

A. Correct.

Q. And you've never done any kind of comparison of complications of symptomatology in patients who've gotten the mechanical cut and the patients who've gotten the laser cut. Correct?

A. Correct.

Id. at 55:16-56:8; *see also* 61:1-8 (has no clinical data). And Dr. Ryder herself admits that her "clinical experience" would not be a reliable basis for: (1) publishing her opinions on this issue; or (2) other physicians to rely upon when making a determination regarding safety or efficacy. *Id.* at 61:1-18, 81:18-82:4.

Simply put, Dr. Ryder cannot base her opinion (that there is no clinical significance to the differences between mechanically cut and laser cut mesh) on her own observations where she does not know—or seem to care—whether or not any particular mesh that she observed was mechanically or laser cut, and where she has made no effort to compare the outcomes of the two meshes. This Court has previously rejected this sort of "I have not seen it, therefore it must not happen" logic. Indeed, in ruling on *Daubert* motions in *Tyree*, the Court held that the "[a]bsence of evidence is not evidence of absence," and refused to allow defendant's expert to opine that certain events do not occur simply because he had not observed them in his practice. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014). By that same unassailable reasoning, Dr. Ryder's claim that, in the few instances that she has seen it in the body, it did not appear to be roped, frayed, curled, or lost particles cannot serve as a reliable scientific basis for rendering the opinions that it does not occur or cannot have a clinical significance.

B. Dr. Ryder' s review of the literature and/or Ethicon documents does not support any opinion regarding mechanical cut versus laser cut mesh.

Similarly, Dr. Ryder finds no support for her opinions on the (lack of) significance between mechanically cut and laser cut mesh in the literature and documents that she—claims to have—reviewed. First, Dr. Ryder admits that there is no support for her opinions in the medical literature. More specifically, after recognizing that there was no citation for the opinion in her report, and after taking time to look through her reliance list, Dr. Ryder testified:

> Q. In No. 5 you said, "There's no evidence to suggest that the safety of TVT mesh is affected by whether it's mechanically cut or laser cut. There is no medical literature that assesses that." Are you changing that opinion today and telling me that there is medical literature that assesses that?
>
> A. No. So I must have been referring to Ethicon documents rather than medical literature.
>
> Q. Okay. So can we -- we agree that there is no basis in the medical literature to establish that the mechanically cut or laser cut. Correct?
>
> THE DEPONENT: I believe that's probably correct.

Id. at 57:10-59:7. Moreover, despite her claim that she was relying on "Ethicon documents" for her opinion, she could not recall or point to a single one:

> Q. Okay. And the sole basis for that is – are your clinical experience with implanting the device over the last 11 years. Correct?
>
> THE DEPONENT: And Ethicon documents I've reviewed.
>
> Q. And which Ethicon documents are those?
>
> A. The ones that related to the laser- versus mechanically cut mesh.
>
> Q. Is there an easy way I can find which of those that you're --
>
> A. No, because I'm not going to be able to tell you --

Id. at 62:10-23; *see also id.* at 71:23-72:9 (no documents cited in report). In other words, when first pressed, Dr. Ryder first backed off the claim that the medical literature supported her

opinion—and when pressed further, she could not point to a single Ethicon document upon which she could rely.

Finally, Dr. Ryder admits that Ethicon's own documents show the differences between the properties of mechanically cut and laser cut mesh. *Id.* at 63:16-64:16. But when questioned about how her (unsupported) opinions are contradicted by Ethicon's own documents, Dr. Ryder simply claims to have not seen the document (despite it being on her reliance list) and says she cannot comment on it. *Id.* at 69:12-70:9.

As such, Dr. Ryder's opinion that there is not clinical significance to the different properties of mechanically cut and laser cut mesh: (1) has no reliable basis in her own experience; (2) admittedly finds no support in the medical literature; and (3) is contradicted by Ethicon's own documents. She should not be permitted to proffer that baseless and unscientific opinion.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Ryder is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and her testimony should be excluded.

Dated: August 1, 2016.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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